

Notice of Allowability**Application No.**

09/403,690

Examiner

Juliet C. Switzer

Applicant(s)

PFEFFER, KLAUS

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to after final amendment filed 5/27/03 and interview 5/29/03.
2. ☒ The allowed claim(s) is/are 21-24, 26-32 and 36-40.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>0503</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Antoinette Konski on 5/29/03.

The application has been amended as follows:

Claim 21 has been replaced with:

21. A method for detection and differentiation of pathogenic enterobacteria in a sample, said method comprising:

isolating nucleic acid from said sample;

adding a set of oligonucleotide primer pairs to said nucleic acid sample wherein said set of oligonucleotide primers comprises at least five oligonucleotide primer pairs wherein, wherein each primer pair specifically amplifies a DNA sequence of a virulence factor/toxin gene characteristic for one each of the subgroups of the pathogenic E. coli strains, said subgroups comprising enterotoxigenic, enteroaggregative, enteroinvasive, enteropathogenic and enterohemorrhagic E. coli strains and wherein for amplification of each subgroup at least one oligonucleotide primer pair is included in said set of oligonucleotide primer pairs, and wherein the set comprises a primer pair that hybridizes to an inv-plasmid of enteroinvasive E. coli and wherein said primer pair is E1-1 : 5' TTT CTG GAT GGT ATG GTG AGG 3' (SEO ID NO: 9)

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and E1-2: 5' CTT GAA CAT AAG GAA ATA AAC 3' (SEQ ID NO: 10) which specifically amplifies a DNA sequence of an *inv* plasmid characteristic for enteroinvasive *E. coli*; and

subjecting said nucleic acid and said set of primer pairs to an amplification process; and detecting the presence of at least one amplified product, wherein the presence of at least one amplified product indicates the presence of at least one pathogenic enterobacteria strain in said sample.

In claim 26, after the phrase "pCVC432 plasmid;", the language ----a labeled oligonucleotide prove specific for the detection of an *inv* plasmid---- was inserted.

Claim 30 was replaced with the following:

30. A set of oligonucleotide primer pairs useful for polymerase chain reaction (PCR) amplification of pathogenic enterobacteria allowing detection and differentiation of pathogenic enterobacteria in a sample wherein following amplification the presence of at least one amplified product indicates the presence of at least one pathogenic enterobacteria strain in said sample, wherein said set comprises at least five primer pairs, wherein each primer pair specifically amplifies a DNA sequence of a virulence factor/toxin gene characteristic for one each of the subgroups of the pathogenic *E. coli* strains, said subgroups comprising enterotoxigenic, enteroaggregative, enteroinvasive, enteropathogenic and enterohemorrhagic *E. coli* strains and wherein for amplification of each subgroup at least one oligonucleotide primer pair is included in said set of oligonucleotide primer pairs, and wherein the set comprises a primer pair that hybridizes to an *inv*-plasmid of enteroinvasive *E. coli* and wherein said primer pair is E1-1 : 5'

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'TTT CTG GAT GGT ATG GTG AGG 3' (SEO ID NO: 9) and E1-2: 5' CTT GAA CAT AAG GAA ATA AAC 3' (SEQ ID NO: 10).

Claim 36 was replaced with the following:

36. A set of oligonucleotide primer pairs and a set of oligonucleotide primer probes useful for diagnosing an enterobacteria infection in samples derived from a living animal body including a human, by real time PCR method, wherein said sets of oligonucleotide primer pairs and oligonucleotide probes allow detection and differentiation of pathogenic enterobacteria in a sample, wherein said set of oligonucleotide primer pairs comprises at least five primer pairs, wherein each primer pair specifically amplifies a DNA sequence of a virulence factor/toxin gene characteristic for one each of the subgroups of the pathogenic E. coli strains, said subgroups comprising enterotoxigenic, enteroaggregative, enteroinvasive, enteropathogenic and enterohemorrhagic E. coli strains and wherein for amplification of each subgroup at least one oligonucleotide primer pair is included in said set of oligonucleotide primer pairs, and wherein the set comprises a primer pair that hybridizes to an inv-plasmid of enteroinvasive E. coli, wherein said primer pair is E1-1 : 5' 'TTT CTG GAT GGT ATG GTG AGG 3' (SEO ID NO: 9) and E1-2: 5' CTT GAA CAT AAG GAA ATA AAC 3' (SEQ ID NO: 10).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the

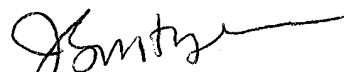
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organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C Switzer
Examiner
Art Unit 1634

May 30, 2003



GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600